

Serial No. 10/781,932

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1st Inventor: Michael N. Helmus

Serial No.: 10/781,932

Filed: 02/20/2004

Title: Biomaterials for Enhanced Healing

Art Unit: 1656

Examiner: Desai, Anand U.

Conf. No.: 9710

Docket No.: 03-081

VIA EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

<p style="text-align: center;">Certificate of Electronic Transmission <u>Under 37 C.F.R. §1.8</u></p> <p>I hereby certify that this correspondence and any document referenced herein are being electronically filed with the USPTO via EFS-Web on December 3, 2009.</p> <p style="text-align: center;"><u>Nancy Joyce Simmons</u> (Printed Name of Person Sending Correspondence)</p> <p style="text-align: center;"><u>/nancy joyce simmons/</u> (Signature)</p>
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**APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING REQUEST FOR
RECONSIDERATION UNDER 37 CFR § 1.705(b)**

Sir:

This is a request for reconsideration of the patent term adjustment of 169 days indicated in the determination of Patent Term Adjustment under 35 U.S.C. § 154(b) that was attached to the Notice of Allowance mailed on September 3, 2009 for the above-referenced patent application. It is respectfully requested that Applicants be granted a minimum patent term adjustment of **472** days.

The issue fee is being paid concurrently herewith.

Applicants submit herewith a "Statement Under 37 CFR §1.705(b)(2)." In accordance with 37 CFR §1.705(b)(1), please charge the fee set forth in 37 CFR §1.18(e) (\$200.00) to Deposit Account No. 50-1047. Any other fees deemed to be due or credit for any overpayment should be directed to Deposit Account Number 50-1047 and authorization is hereby given to charge such account.

Serial No. 10/781,932

Dated: December 3, 2009
Attorney for Applicant
Mayer & Williams, PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 703-433-2362

Respectfully submitted,

/David B. Bonham/
David B. Bonham
Registration No. 34,297

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Nancy Joyce Simmons
(Printed Name of Person Sending Correspondence)

/nancy joyce simmons/
(Signature)

STATEMENT UNDER 37 CFR § 1.705(b)(2)

Sir:

This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR § 1.705(b)” for the above-referenced patent application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of **472** days.

The patent term adjustment on the Determination of Patent Term Adjustment Under 35 U.S.C. § 154(b) ("PTAS Sheet") that was attached to the Notice of Allowance and which is submitted herewith as Exhibit A is 169 days. A copy of the Office's calculation for the 169 days, printed from PAIR, is submitted herewith as Exhibit B.

This determination of 169 days is in error in that, pursuant to 35 U.S.C. §154(b), the Office failed to take certain action within the time frame specified in 37 CFR § 1.702(a) and failed to issue a patent within three years of the actual filing date of the above-referenced application in accordance with 37 CFR §1.702(b). See *Wyeth v. Dudas*, 88 U.S.Q.P. 2d 1538 (D.D.C. 2008). Applicants assert that pursuant to the decision in *Wyeth v. Dudas*, 580 F. Supp.

2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008), a PTO delay under 35 U.S.C. 154(b)(1)(A) overlaps with a delay under 35 U.S.C. 154(b)(1)(B) only if the delays occur on the same day.

The following is a statement of the facts involved specifying the correct patent term adjustment and the basis for the adjustment under 37 CFR § 1.702, including the relevant dates as specified in 37 CFR § 1.703(a)-(e) for which adjustment is sought, and the adjustment as specified in 37 CFR § 1.703(f) to which the patent is entitled, and any circumstances during the prosecution of the application resulting in the patent that constitutes a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 CFR § 1.704. **The application is not subject to a terminal disclaimer.**

A. 14 Month Delay under 37 CFR §§ 1.702(a) and 1.703(a)

Pursuant to 37 CFR §1.702(a)(1) and 1.703(a)(1), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date (i.e., February 20, 2004) (hereinafter "14 Month Delay"). Applicants state that a reduction of patent term adjustment for Applicants' failure to engage in reasonable efforts to conclude prosecution pursuant to 37 C.F.R. § 1.704 totals "0" days. Applicants agree with the Office's calculation shown in Exhibit B that the 14 Month Delay is **393** days. Because the Office failed to mail an action under 35 U.S.C. §132 until May 15, 2006, Applicants are entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after the date on which the above-referenced application was filed under 35 U.S.C. § 111(a), i.e., April 21, 2005, and ending on the date of mailing of an action under 35 U.S.C. § 132, i.e., May 15, 2006. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is **393** days.

B. 3 Year Delay under 37 CFR §§ 1.702(b) and 1.703(b)

The patentees are entitled to a period of patent term adjustment pursuant to 37 C.F.R. §§ 1.702(b) and 1.703(b) due to examination delay from the number of days in the period beginning on the day after the date that is three years after February 20, 2004, when the above-referenced application was filed under 35 U.S.C. § 111(a) (i.e., February 21, 2007) and ending on the date a Request for Continued Prosecution was filed (i.e., December 21, 2007), not

including several categories of exceptions stated in 35 U.S.C. § 154(b)(1)(B)(i)-(iii) (“3-Year Delay”). The patentees disagree with the Office’s calculation shown in Exhibit A that the 3-Year Delay is 0 days (net of overlap; see *infra*); instead, the correct 3-Year Delay is **303** days.

A Request for Continued Prosecution was filed in this application on December 21, 2007. Applicants are entitled to a period of patent term adjustment from February 21, 2007 until December 21, 2007, for a total of **303** days.

C. Exclusion of Overlapping Delay under 37 C.F.R. § 1.703(f)

Applicants are not entitled to a period of patent term adjustment to the extent that the periods in 37 CFR § 1.702 (4 Month Delay) overlap pursuant to 37 CFR § 1.703(f) (“Overlapping Delay”). The Office calculated 0 days of Overlapping Delay (Exhibit B). Applicants agree with the Office's calculation.

D. Exclusion of Applicant Delay under 37 CFR §§ 1.703(f) and 1.704

Applicants are not entitled to a period of patent term adjustment to the extent that they failed to engage in reasonable efforts to conclude prosecution of the application pursuant to 37 CFR §§ 1.703(f) and 1.704 (“Applicant Delay”). Applicants agree with the Office’s calculation of Applicant Delays of **224** days as shown in Exhibit B.

E. Total Patent Term Adjustment

In accordance with the decision in *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008), a PTO delay under 35 U.S.C. 154(b)(1)(A) overlaps with a delay under 35 U.S.C. 154(b)(1)(B) only if the delays occur on the same day. Thus, pursuant to 37 CFR § 1.703(f), the total patent term adjustment is **393** days of 14 Month Delay, plus **303** days of 3 Years Delay, minus 0 days of Overlapping Delay, minus **224** days of Applicants’ Delay, for a total of **472** days.

F. Conclusion

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of **472 days**, which may be extended or reduced based on the actual date of issuance of a patent for the above-referenced application.

Dated: December 3, 2009
Attorney for Applicant
Mayer & Williams, PC
251 North Avenue West, 2nd Floor
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Fax: 703-433-2362

Respectfully submitted,

/David B. Bonham/
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EXHIBIT A



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,932	02/20/2004	Michael N. Helmus	03-081	9710
27774	7590	09/03/2009	EXAMINER	
MAYER & WILLIAMS PC 251 NORTH AVENUE WEST 2ND FLOOR WESTFIELD, NJ 07090			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 09/03/2009				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 169 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 169 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Serial No. 10/781,932

EXHIBIT B

Patent Term Adjustments






Patent Term Adjustment (PTA) for Application Number: 10/781,932

Filing or 371(c) Date:	02-20-2004	USPTO Delay (PTO) Delay (days):	393
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	224
Post-Issue Petitions (days):	+0	Total PTA (days):	169
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-03-2009	Mail Notice of Allowance		
09-01-2009	Document Verification		
08-31-2009	Notice of Allowance Data Verification Completed		
08-19-2009	Date Forwarded to Examiner		
08-13-2009	Amendment after Final Rejection		30
08-13-2009	Request for Extension of Time - Granted		⚡
07-13-2009	Mail Advisory Action (PTOL - 303)		⚡
07-13-2009	Advisory Action (PTOL-303)		⚡
06-17-2009	Date Forwarded to Examiner		⚡
06-15-2009	Amendment after Final Rejection		⚡
04-27-2009	Change in Power of Attorney (May Include Associate POA)		⚡
04-23-2009	Correspondence Address Change		⚡
04-14-2009	Mail Final Rejection (PTOL - 326)		⚡
04-13-2009	Final Rejection		
02-10-2009	Date Forwarded to Examiner		
02-02-2009	Response after Non-Final Action		31
02-02-2009	Request for Extension of Time - Granted		⚡
10-14-2008	Change in Power of Attorney (May Include Associate POA)		⚡
10-11-2008	Correspondence Address Change		⚡
10-02-2008	Mail Non-Final Rejection		⚡
09-29-2008	Non-Final Rejection		
07-24-2008	Date Forwarded to Examiner		
06-19-2008	Response after Non-Final Action		
03-21-2008	Mail Non-Final Rejection		
03-17-2008	Non-Final Rejection		
01-02-2008	Date Forwarded to Examiner		
01-02-2008	Date Forwarded to Examiner		
12-21-2007	Request for Continued Examination (RCE)		56
01-02-2008	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		⚡
12-21-2007	Workflow - Request for RCE - Begin		⚡
11-16-2007	Mail Advisory Action (PTOL - 303)		⚡
11-13-2007	Advisory Action (PTOL-303)		⚡
10-30-2007	Date Forwarded to Examiner		⚡
10-26-2007	Amendment after Final Rejection		⚡
07-26-2007	Mail Final Rejection (PTOL - 326)		⚡

07-23-2007	Final Rejection		
05-15-2007	Date Forwarded to Examiner		
05-10-2007	Response after Non-Final Action		107
04-13-2007	Mail Notice of Informal or Non-Responsive Amendment		✎
02-01-2007	Date Forwarded to Examiner		✎
01-23-2007	Informal or Non-Responsive Amendment after Examiner Action		✎
01-23-2007	Response after Non-Final Action		✎
10-23-2006	Mail Non-Final Rejection		
10-16-2006	Non-Final Rejection		
10-12-2006	Case Docketed to Examiner in GAU		
09-01-2005	Information Disclosure Statement considered		
08-24-2006	Date Forwarded to Examiner		
08-18-2006	Response to Election / Restriction Filed		
08-18-2006	Request for Extension of Time - Granted		
05-18-2006	Mail Restriction Requirement	393	
05-15-2006	Requirement for Restriction / Election	✎	
04-20-2006	IFW TSS Processing by Tech Center Complete	✎	
09-01-2005	Reference capture on IDS	✎	
09-01-2005	Information Disclosure Statement (IDS) Filed	✎	
09-01-2005	Information Disclosure Statement (IDS) Filed	✎	
12-23-2005	Preliminary Amendment	✎	
04-20-2006	Case Docketed to Examiner in GAU	✎	
03-08-2006	Application Return from OIPE	✎	
01-19-2005	Application Return from OIPE	✎	
01-19-2005	Application Return TO OIPE	✎	
01-18-2005	Application Return from OIPE	✎	
01-19-2005	Application Is Now Complete	✎	
01-18-2005	Application Return TO OIPE	✎	
01-18-2005	Application Return from OIPE	✎	
01-18-2005	Application Is Now Complete	✎	
12-23-2004	Additional Application Filing Fees	✎	
02-20-2004	Claim Preliminary Amendment	✎	
12-23-2004	A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in	✎	
01-06-2005	CRF Is Good Technically / Entered into Database	✎	
11-02-2004	SEQUENCE ERRORS	✎	
11-02-2004	Additional Application Filing Fees	✎	
09-02-2004	Pre-Exam Office Action Withdrawn	✎	
11-02-2004	Application Return TO OIPE	✎	
09-28-2004	Application Return TO OIPE	✎	
09-02-2004	Application Return from OIPE	✎	
09-02-2004	Application Return TO OIPE	✎	
09-02-2004	Application Dispatched from OIPE	✎	
09-02-2004	Application Is Now Complete	✎	
08-13-2004	Payment of additional filing fee/Preexam	✎	
08-13-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	✎	

05-13-2004	Notice Mailed--Application Incomplete--Filing Date Assigned	
04-02-2004	Cleared by L&R (LARS)	
03-25-2004	Referred to Level 2 (LARS) by OIPE CSR	
03-04-2004	IFW Scan & PACR Auto Security Review	
02-20-2004	Initial Exam Team nn	

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